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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/803,557	03/17/2004	Doug Hui Huang	034827-1402	6217

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EXAMINER

HORLICK, KENNETH R

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 09/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/803,557

Applicant(s)

HUANG, DOUG HUI

Examiner

Kenneth R. Horlick

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-11 and 13-16 is/are rejected.
- 7) ☒ Claim(s) 4 and 12 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/15/04 (3 pages)</u> . | 6) <input type="checkbox"/> Other: ____. |

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1. The specification is objected to because of the following informality: the continuation information must be updated to indicate the issue of the parent '870 application as U.S. Patent No. 6,727,354.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This claim is confusing because of the language "wherein comprise". Correction is required.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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4. Claims 1-3, 5, 7, 11, 13, 15, and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Nguyen et al. (US 6,171,788).

These claims are drawn to methods of detecting a TIGR genotype via single-nucleotide extension assays.

Nguyen et al. disclose such methods; see columns 2, 3, 6, 26, 27, and 30-33. Specifically, determination of a TIGR genotype or polymorphism is taught in column 2 at lines 54-56; the TIGR genotype MT-1 is taught in column 6 at lines 35-36; diagnosis or prognosis of glaucoma and selection of treatment regimen is taught in columns 26 and 27; polymerase chain reaction is disclosed at the top of column 31; and single-nucleotide extension assays using labeled ddNTPs are taught in column 30, lines 26-60.

5. Claims 1-3, 5, 7, 11, 13, 15, and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Stone et al. (US 6,403,307).

Stone et al. disclose such methods; see columns 5-6, 43-44, 50-53, 56-57, and 60-61. Specifically, determination of a TIGR genotype or polymorphism is taught in columns 5-6; the TIGR genotype T377M is taught in column 6 in Table 1, #8; diagnosis or prognosis of glaucoma and selection of treatment regimen is taught in columns 50-51 and 60; polymerase chain reaction is disclosed in column 53, lines 19-22; and single-nucleotide extension assays using labeled ddNTPs are taught in column 56, line 40 to column 57, line 32.

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6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6, 8-10, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over either of Nguyen et al. or Stone et al.

These claims are drawn to methods as described and rejected above, further limited with respect to capillary electrophoresis, fluorescently labeled ddNTPs or sets thereof comprising different and distinguishable labels, or obtaining samples by scraping within the buccal cavity.

Although these limitations are not explicitly taught in the primary references, one of ordinary skill in the art would have been motivated to apply them in the methods of Nguyen et al. or Stone et al. because they were unquestionably conventional in the art and would have provided known and expected benefits: capillary electrophoresis and sets of distinguishably-labeled fluorescent ddNTPs were conventional in nucleic acid separations such as sequencing and polymorphism detection; and scraping within the buccal cavity was a conventional, non-invasive means of providing samples for nucleic acid analysis. Thus, such further limitations surely do not contribute towards patentability. It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to carry out the claimed methods.

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7. Claims 4 and 12 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. These claims require the use of an oligonucleotide of one of SEQ ID NO:1-8, which oligonucleotide was found to be free of the prior art in the prosecution of the parent '870 application.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kenneth R. Horlick whose telephone number is 571-272-0784. The examiner can normally be reached on Monday-Thursday 6:30AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Kenneth R Horlick, Ph.D.

Primary Examiner

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09/12/06